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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,558	09/02/2005	Jorg Hacker	H&U122	9541
Marlana Titus Nash & Titus 6005 Riggs Road Laytonsville, MD 20882			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 10/19/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,558

Applicant(s)

HACKER ET AL.

Examiner

Michele K. Joike

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed August 11, 2010. Claims 1-6 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed May 11, 2010 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Uraji et al, in view of Blum-Oehler et al, Trevors et al and in further view of Gasson et al.

Claims 2-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Uraji et al in view of Blum-Oehler et al, in view of Trevors et al and Gasson et al and in further view of Alexeyev et al.

Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)

Applicant's arguments filed August 11, 2010 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

The Examiner needed to string four or five references to make the 103(a) rejection. None of the references specifically teach the curing of strain DSM 6601 or the desire to cure pMut1 and pMut2.

Gasson has been cited to fill in a "gap" in the string of cited art to show that a plasmid can be cured from a host. Not every curing method is suitable for every species. Gasson is nearly irrelevant to the method our inventors adapted.

Uraji deals with Agrobacterium. Agrobacterium and E. coli are two completely different organisms, and the removal or even desirability of removal of the plasmids would not be viewed by someone having ordinary skill in this art as being equivalent or even suggestive of each other. They do not suggest curing of plasmids from other species. Also, the introduction of two sacB genes into the pMut plasmids is an affirmative requirement. Uraji does not teach the introduction of two sacB genes.

Blum-Oehler merely represents the problem that is solved by the instant invention. The Examiner is using hindsight reasoning.

Applicant's arguments have not been found persuasive for the following reasons.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection

does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). The Examiner agrees that none of the references individually teach the curing of strain DSM 6601 or the desire to cure pMut1 and pMut2, that's why she used 4-5 references.

The Examiner cited Uraji to show that a plasmid can be cured from a host using the sacB gene. Gasson was used to show that multiple plasmids can be cured from a host cell. Uraji teaches a curing method wherein bacteria are transformed with a plasmid containing an introduced sacB gene and an introduced kanamycin resistance cassette. The bacterium already contains a second plasmid (without the sacB gene). The bacteria is then cured of both plasmids by culturing the cells overnight in LB supplemented with sucrose (also called saccharose), and then were grown on media supplemented with kanamycin. As already established, Uraji does not teach DSM 6601 or the pMut plasmids. However, it does teach a curing method that differs from claim only in that a resistance gene and sacB gene are introduced into the second plasmid, as it is already present in the cell. This is the method that is relevant. Again, Gasson is only used to demonstrate that a cell can be cured of more than one plasmid.

Uraji teaches a curing method. Trevors teaches different types of curing in different bacteria. While not all curing methods will cure all plasmids in all strains, *E. coli* is a very common and well-used bacterium. Trevors teaches the use of the bacterium in several curing methods. Uraji also teaches that a plasmid containing the sacB gene can be moved from *E. coli* to *Agrobacterium*, which suggests that sacB can be used on *E. coli*. There is no indication that the method of Uraji would not work in

other bacteria, and Agrobacteria are gram negative bacteria, like E. coli. Uraji does not teach the introduction of two sacB genes, it only teaches the introduction of one sacB gene. However, they do teach that sacB should be in a plasmid being introduced into the cell that is being cured. They also teach the desirability of using the sacB gene. They state that it is useful for counter-selection as well as selection, and that a curing method based on incompatibility is more efficient and convenient than the conventional methods. Curing DSM 6601 is desirable because the pMut plasmids are cryptic, and extraneous DNA in a cell is often undesirable. There are a finite number of curing methods and curing strains of plasmids using sacB is a known efficient and convenient curing method. Therefore, it would have been obvious to try sacB in the second plasmid because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. Knowing that scab was used successfully by Uraji to cure the first plasmid, there is a reasonable expectation of success that that second plasmid could be cured.

Blum-Oehler is used to teach that pMut1 and pMut2 are cryptic with no apparent benefit to the host. Combined with the other cited references, curing DSM 6601 of the plasmids is taught.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Allowable Subject Matter

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/
Primary Examiner, Art Unit 1636

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